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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,911	12/01/2000	Scott R Presnell	99-93	2372

7590 07/23/2002  
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EXAMINER

ROARK, JESSICA H

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/23/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/728,911

Applicant(s)

PRESNELL ET AL.

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-42 and 47-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-3,8-42 and 47-71 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1644

### DETAILED ACTION

1. Applicant's amendment, filed 4/22/02 (Paper No. 8) is acknowledged.  
Claims 4-7 and 43-46 have been cancelled.  
Claims 2-3, 50 and 54 have been amended.  
Claims 67-71 have been added.  
Claims 1-3, 8-42 and 47-71 are pending.
2. Applicant's election without traverse of Group I (claims 1-7, 19-20 and 43-54) in Paper No. 7 is acknowledged.
3. After further review and consideration, it appears that certain aspects of the original restriction were in error. In addition, the Requirement of record in Paper No. 6 was made prior to the addition of newly added claims 67-71. In order to correct and clarify the Record, the Restriction Requirement set forth in Paper No. 6 is hereby VACATED. A new Restriction Requirement follows.

#### *Restriction Requirement*

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-3, 19-20, 47-53 and 67-70, drawn to forms of a polypeptide comprising SEQ ID NO:2 or fragments thereof, fusion proteins and complexes comprising said polypeptides; classified in Class 530, subclasses 350 and 387.3.
  - II. Claims 8-15, 21-42, 54 and 71, drawn a polynucleotide sequence encoding forms of a polypeptide comprising SEQ ID NO:2 or fragments, fusion proteins and complexes thereof; DNA constructs, vectors, host cells, and methods of producing these polypeptides, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
  - III. Claims 16-17 and 55-58, drawn to a form of an antibody to a polypeptide comprising SEQ ID NO:2, fragments of SEQ ID NO:2 or complexes comprising said polypeptides and methods of producing these antibodies; classified in Class 530, subclass 387.1 and Class 435, subclass 41.
  - IV. Claim 18, drawn to an anti-idiotypic antibody, classified in Class 530, subclass 387.2.
  - V. Claims 59-61, drawn to a method of inhibiting IL-TIF induced cellular proliferation in a cell culture using a composition comprising a soluble form of the polypeptide of SEQ ID NO:2, classified in Class 424, subclass 184.1.
  - VI. Claims 62-63, drawn to a method of suppressing inflammation using a composition comprising a soluble form of the polypeptide of SEQ ID NO:2, classified in Class 424, subclass 184.1.

Art Unit: 1644

VII. Claim 64, drawn to a method of detecting a genetic abnormality in a genetic sample using a polynucleotide derived from SEQ ID NO:1, classified in Class 435, subclass 6.

VIII. Claim 65, drawn to a method of detecting cancer using an antibody to SEQ ID NO:2 or a fragment thereof, classified in Class 435, subclass 7.1.

IX. Claim 66, drawn to a method of detecting a cancer in a tissue sample using a polynucleotide derived from SEQ ID NO:1, classified in Class 435, subclass 6.

5. Groups I, II, III and IV are different products. Nucleic acids, polypeptides, antibodies to the polypeptide and anti-idiotypic antibodies differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

6. Groups II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

7. Groups V, VI, VII, VIII and IX are different methods. Each method differs with respect to one or more of the ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

8. Groups (I and V/VI), (II and VII/IX) and (III and VIII), respectively, are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the polypeptide of Group I can be used to immunize animals to produce an antibody; the polynucleotide of Group II can be used to express the polypeptide; and the antibody of Group III can be used for affinity purification, in addition to the methods of inhibiting and detecting recited.

9. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. A different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Art Unit: 1644

### *Species Election*

10. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

*If Group I, II or III is elected, Applicant is required to elect a specific form of the receptor complex (homodimeric, heterodimeric or multimeric) comprising a specific combination of components (either no additional components if homodimeric; or a particular Class I or a particular Class II cytokine receptor, if heterodimeric or multimeric) as appropriate for the elected group.*

These species are distinct because the components of the receptor complex, the individual polynucleotides encoding the components of the receptor complex, and the antibodies to the forms of the polypeptide receptor complex each differ with respect to their structure and physiochemical properties; thus each represents patentably distinct subject matter. Currently, no claims are generic.

It is noted that not all claims within Groups I/II/III are affected by the species election applying to the nature of the receptor complex. Claims not affected by the species election will be examined together with those claims to the specific receptor complex elected.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1644

14. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.  
Patent Examiner  
Technology Center 1600  
July 22, 2002

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7/22/02